Serial No.: 09/911,353
Docket No.: VAS-5644
Amendment dated June 22, 2004
Responsive to Office Action of February 25, 2004

REMARKS/ARGUMENTS

Prior to the present Office Action, claims 1-16 were pending.

Claims 1, 4-7, and 9-11 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Vilendrer (U.S. 5,670,708) in view of Dancu, et al (WO 02/32224). Applicants respectfully assert that the present invention as claimed is not obvious over Vilendrer in combination with Dancu, et al., and further that the combination is not suggested by either reference.

Prior to a discussion of the merits of the rejection, Applicants note the following relevant dates:

1. Dancu, et al. was filed as a provisional on Saturday, 10/6/00
2. The present application was filed on 7/23/01
3. Dancu, et al. was filed in the U.S. on Tuesday, 10/9/01 (US 2002/0042701)
4. Dancu, et al. was filed in the PCT on Tuesday, 10/9/01 (WO 02/32224)

(Note: Columbus Day was celebrated on Monday, October 8, 2001, and therefore U.S. Application No. 2002/0042701 claims valid priority under 35 U.S.C. §119(e) to the provisional application)

Only the filing date of the Dancu provisional application (hereafter "the Dancu provisional") predates the filing date of the present invention (also the *prima facie* "invention date" in the absence of earlier evidence). Therefore, it is only the disclosure of *the Dancu provisional* that can be used in the substance of any prior art rejection (including in the context of 35 U.S.C. §§102(e)/103(a)), and the remarks below are relative to the combination of Vilendrer with the Dancu provisional. Examiner Jackson has kindly sent the Dancu provisional disclosure via facsimile to the Applicants, and it is attached hereto for the sake of full disclosure and reciprocal understanding. Applicants respectfully request that Examiner Jackson make the Dancu provisional officially "of record" in the present application so that its prior art significance is noted on the cover of any patent that may issue herefrom.

Discussion of Vilendrer

Vilendrer discloses an intravascular prosthesis fatigue tester which is best seen in cross-section in Figure 6. In the description in column 2, lines 10-51, the fatigue tester utilizes a fluid conduit that includes "at least one elastic simulated arterial/venous tube which approximates the geometry of a healthy human arterial/venous vessel." The prosthesis is placed within the tube which is pressurized with a temperature controlled fluid and the radial dilation thereof is measured with a compliance transducer. In column 4, line 25, the tube is said to be made from a "flexible latex rubber."

The system disclosed in Vilendrer is manufactured by Endura-Tec Systems Corporation of Minnesota, and has been used for a number of years in the testing of such prostheses. Indeed, such systems were described in the background of present application at the bottom of column 3. The systems only utilize synthetic tubes as the conduits for testing the prostheses. There is no suggestion in Vilendrer to replace the four latex tubes in the illustrated device with anything but latex, and as mentioned in the background of the present application at page 3, line 17, such prior art systems typically use compliant tubes of latex or silicone. One obvious reason for utilizing artificial tubes is the ability to easily control and therefore rely on the physical characteristics of the tubes.

Discussion of the Dancu Provisional

The Examiner has admitted that Vilendrer does not disclose an animal tissue tube, and cites Dancu, et al. to supply such a missing element in the rejection of claims 1 and 9 and their dependents. However, the Dancu provisional does not disclose an animal tissue tube as a pressurized conduit for compliance testing. Applicants note that in the present claims 1 and 9 it is the tube within which the stent or stented graft is mounted that is made of animal tissue.

The Dancu provisional discloses a hemodynamic simulator that reproduces "real" patterns of physiologic blood flow in a patent flow testing tube. The flow testing tube is elastic silicone coated with endothelial cells (EC). The main emphasis in the disclosure is the idea of

uncoupling, in the simulator, the flow-generated components of wall shear stress (WSS) and circumferential strain (CS) that together affect the response of EC in blood vessels. This permits "independent control of the magnitude and phase of the pulsatile WSS and CS," which in turn obtains a better understanding of EC biological response. Another use of the simulator is in tissue engineering to test or train the function of bypass vessels prior to coronary bypass surgery. For instance, "hemodynamical unstrenuous" human saphenous veins may be trained in the "strenuous hemodynamic environment of the coronary arteries."

Nowhere in the Danku provisional is there disclosure or a suggestion to use animal tissue as a tester tube. The Examiner should note that there is a distinction made in the present application at the bottom of page 10 between "animal" and "human" in the context of the tester tubes. Furthermore, nowhere in the Danku provisional is there disclosure or a suggestion of mounting a vascular graft within a tester tube. The Danku provisional only pertains to subjecting patent tubes without anything emplaced therein to various flow conditions. Consequently, the Danku provisional adds nothing to Vilendrer to render claim 1 obvious.

Discussion of Claims 1 and 9

Claim 1 of the present application provides a compliance testing assembly which has an animal tissue tube and a pre-tester including fixtures sealingly coupled to the free ends of the tube and having a fluid supply in communication with the tube lumen. A stent or stent graft is positioned within the animal tissue tube which can be subjected to fluid flow for testing the compliance of the prosthesis within the tube. Vilendrer does not disclose the use of an animal tissue tube and does not suggest substituting one for the latex tube disclosed. Based on the disclosure of the Danku provisional, one of skill in the art would not be motivated to utilize an animal tissue tube for the flow or pulsatile testing. As mentioned, the Danku provisional merely subjects patent tubes to particular flow conditions to either determine the response of endothelial cells lining silicone tubes or to test or train "bypass vessels," none of which are disclosed to be animal tubes.

Claim 9 provides a method of testing the compliance of a stent or stent graft including using an animal tissue tube and flowing a fluid therethrough. This method is not taught by Vilendrer alone or in combination with the Danku provisional. As stated above, Vilendrer does not disclose or suggest the use of an animal tissue tube, and neither does the Danku provisional. Accordingly, claims 9-16 are believed allowable over the cited references.

Moreover, the combination of the two references is not suggested by either. First, there is no mention of modifying the tester tubes in Vilendrer to be anything but latex. Conversely, the Danku provisional does not suggest using any materials other than synthetic or human for the test tubes, and does not propose testing stents or stent grafts therein. In other words, there is no *prima facie* motivation to combine the two references.

Claims 2-3, 8, and 12-16 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Vilendrer in view of Dancu, et al., and further in view of several tertiary references. Applicants respectfully assert that, on the basis of the foregoing arguments, claims 1 and 9 are allowable and therefore their dependents are allowable as well.

In view of the foregoing remarks, claims 1-16 are allowable.

Respectfully submitted,

Date: June 22, 2004

Guy Cumberbatch, Reg. No. 36,114
Telephone: (773) 857-7634
c/o Debra Condino, Reg. No. 31,007
Edwards Lifesciences LLC
Law Department
One Edwards Way
Irvine, California 92614
Telephone: (949) 250-6803
Facsimile: (949) 250-6850
Customer No. 30452